STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 30 June 2004 please refer to module 8B

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
Update of Summary of Product Characteristics (section 4.5) and Package Leaflet to include a possible interaction between bexarotene and tamoxifen.	II/02	II	27.06.02	17.10.02
Change in the address of the MAH	I/03	I	11.06.02	11.07.02
Addition of a new supplier for gelatin and TSE Compliance	I/04	I	19.12.02	-
Minor change in package leaflet not connected with the SPC (Art. 61.3 Notification)	N/05	N	15.05.03	04.06.03
Change in the name and/or address of a manufacturer of the finished product	IA/06	IA	23.03.04	-
Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	N/07	N	14.06.04	-

[1] In accordance with Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended: **I** refers to a minor variation (Type I variation); **II** refers to a major variation (Type II variation); **I/II** refers to a minor variation following the procedure set out in Article 6, 7 and 8 of the Regulation; **X** refers to an Annex II application.
T refers to a transfer of a Marketing Authorisation in accordance with Commission Regulation (EC) No 2141/96 of 7 November 1996.
N refers to a notification in accordance with Article 10(3) of Council Directive 92/27/EEC of 31 March 1992.

[2] For Notifications and Type I variations, the date of entry into force of the change is the EMEA Notification date. The Commission Decision will be amended accordingly.

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